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| 10/537,354 | 06/06/2005 | Chih-Chang Chu | CHUC3006 | 2654 |

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| EXAMINER | |
|---|---|
| HEINCER, LIAM J | |

| ART UNIT | PAPER NUMBER |
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| 1796 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/537,354 | CHU ET AL. | |
| | Examiner | Art Unit | |
| | Liam J. Heincer | 1796 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *22 January 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-5* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hokkoku et al. (US Pat. 4,032,488) in view of Uladag et al. (US 2002/0015734).

Considering Claims 1 and 2: Hokkoku et al. teaches a hydrogel (14:16-39) formed by UV irradiation/photocrosslinking (11:9-14) a dextran-maleic acid monoester (2:25-48 and 3:38-40) and an acrylamide component (4:9-12), wherein the dextran-maleic acid monoester comprises 20 to 65% by weight of the composition and the acrylamide component comprises 80 to 35% by weight (4:51-56).

Hokkoku et al. does not teach the acrylamide component as being N-isopropylacrylamide. However, Uladag et al. teaches using N-isopropylacrylamide (¶0012) as an acrylamide component of a hydrogel (¶0060). Hokkoku et al. and Uladag et al. are combinable as they are concerned with the same field of endeavor, namely

hydrogels for carrying bioactive agents. It would have been obvious to a person having ordinary skill in the art at the time of invention to have used the N-isopropylacrylamide of Uladag et al. in the composition of Hokkoku et al., and the motivation to do so would have been, as Uladag et al. suggests, polymers made from N-isopropylacrylamide have a predictable polymer LCST (¶0014).

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hokkoku et al. (US Pat. 4,032,488) in view of Uladag et al. (US 2002/0015734).
Considering Claim 5: Hokkoku et al. teaches a hydrogel forming system (14:16-39) comprising a dextran-maleic acid monoester (2:25-48 and 3:38-40) and an acrylamide component (4:9-12), wherein the dextran-maleic acid monoester comprises 10 to 75% by weight of the composition and the acrylamide component comprises 90 to 25% by weight (4:51-56).

Hokkoku et al. does not teach the acrylamide component as being N-isopropylacrylamide. However, Uladag et al. teaches using N-isopropylacrylamide (¶0012) as an acrylamide component of a hydrogel (¶0060). Hokkoku et al. and Uladag et al. are combinable as they are concerned with the same field of endeavor, namely hydrogels for carrying bioactive agents. It would have been obvious to a person having ordinary skill in the art at the time of invention to have used the N-isopropylacrylamide of Uladag et al. in the system of Hokkoku et al., and the motivation to do so would have been, as Uladag et al. suggests, polymers made from N-isopropylacrylamide have a predictable polymer LCST (¶0014).

Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hokkoku et al. (US Pat. 4,032,488) in view of Uladag et al. (US 2002/0015734) as applied to claim 2 above, and further in view of Kim et al. (WO 00/12619) as evidenced by Lewis (Hawley's Condensed Chemical Dictionary).

Chen et al. teaches the basic composition of claim 2 as stated above.
Considering Claim 3: Hokkoku et al. does not teach the dextran-maleic acid monoester as having an average degree of substitution ranging from 0.85 to 0.95 and a weight

average molecular weight ranging from 65,000 to 75,000 on a dextran basis. However, Kim et al. does teach a dextran-maleic acid monoester having an average degree of substitution ranging from 0.85 to 0.95 and a weight average molecular weight ranging from 65,000 to 75,000 on a dextran basis (pg. 6, ¶3). Hokkoku et al. and Kim et al. are combinable as they are concerned with the same field of endeavor, namely dextran monoester containing hydrogels. It would have been obvious to a person having ordinary skill in the art at the time of the invention to have used a dextran-maleic acid monoester having the specifications of Kim et al. in the hydrogel of Hokkoku et al. and the motivation to do so would have been, as Kim et al. suggests, to provide a hydrogel for encapsulation of virus (pg. 7, ¶5) and, as Lewis suggests, the molecular weight is the clinical standard (¶1).

Considering Claim 4: The Office realizes that all of the claimed effects or physical properties are not positively stated by the reference(s). However, the reference(s) teaches all of the claimed ingredients. Therefore, the claimed effects and physical properties, i.e. the lower critical solution temperature would implicitly be achieved by a composition with all the claimed ingredients. If it is the applicant's position that this would not be the case: (1) evidence would need to be provided to support the applicant's position; and (2) it would be the Office's position that the application contains inadequate disclosure that there is no teaching as to how to obtain the claimed properties with only the claimed ingredients.

### ***Response to Arguments***

Applicant's arguments filed January 22, 2008 have been fully considered but they are not persuasive, because:

A) Applicants argument that art does not teach the concept of a pH sensitve, temperature sensitive hydrogel is not persuasive. In response to applicant's arguments, the recitation "hydrogel that changes its shape and volume in response to change in pH and in response to change in temperature" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended

use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). Additionally, even if the pH and temperature sensitivity were added to the body of the cliam, a hydrogel having the claimed monomers would implicitly have the claimed properties, as the properties are imparted by the monomers.

B) Applicants argument that the citation of column 14, lines 16-39 are not applicable is not persuasive. While the specific example given in this citation is not the same as the claimed invention, it is applicable as a general example of forming hydrogels from the crosslinked polymers of Hokkoku et al. Additionally, Hokkoku et al. is concerned with making contact lenses (2:5) which are traditionally made of hydrogel materials. Therefore, a person having ordinary skill in the art at the time of invention would have known that the polymers of Hokkoku et al. could be used in a hydrogel, even if there is not an explicit example given with the claimed monomers.

C) Applicants argument that there are a multitude of possible combinations is not persuasive. While there are several acids to choose from, a person having ordinary skill in the art at the time of invention would not have found it too difficult to test fourteen acids, using modern laboratory equipment, to see which one provided the desired result. As Hokkoku et al. is concerned with the delivery of drugs in the body, a person having ordinary skill in the art at the time of invention would have known to look for hydrogels with drug delivery properties, such as environmentally controlled release.

Additionally, the combination lock analogy is misleading. A person having ordinary skill in the art at the time of invention would not have been choosing from 85 olefinic compounds. As Hokkuku et al. and Uludag et al. are both concerned with delivery of bioactive molecules in the body, a person having ordinary skill in the art at the time of invention would have looked to the teachings of Uludag et al. when choosing the olefinic polymer. As Uludag et al. teaches the desirable properties of N-isopropylacrylamide, they would have been motivated to choose N-isopropylacrylamide amide as the olefinic polymer due to its predictable polymer LCST (¶0014). The

inclusion of acrylamide in the list of possible olefinic monomers in Hokkuku et al. would have given a reasonable expectation of success that N-isopropylacrylamide would function in the hydrogel of Hokkuku et al.

D) Applicant's argument that the claimed LCST is not implicit is not persuasive. While Figure 1 shows that the polymer with a dextran ester value of over 65% would not have the claimed property, there is no evidence to show that the polymer as taught in claim 3 would not have the claimed property.

### *Conclusion*

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

### *Correspondence*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Liam J. Heincer whose telephone number is 571-270-3297. The examiner can normally be reached on Monday thru Friday 7:30 to 5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Eashoo can be reached on 571-272-1197. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MARK EASHOO/ LJH
Supervisory Patent Examiner, Art Unit 1796 April 17, 2008
22-Apr-08